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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/539,421  | 06/20/2005  | Hideaki Yamaoka        | 10921.333USWO       | 1084             |
| 52835 7590 12/09/2008<br>HAMRE, SCHUMANN, MUELLER & LARSON, P.C.<br>P.O. BOX 2902<br>MINNEAPOLIS, MN 55402-0902 |             |                        |                     |                  |
| EXAMINER<br>DIETERLE, JENNIFER M  |             |                        |                     |                  |
| ART UNIT<br>4111  |             | PAPER NUMBER           |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/539,421

**Applicant(s)**

YAMAOKA, HIDEAKI

**Examiner**

Jennifer Dieterle

**Art Unit**

4111

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 06/20/2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

1. In figure 1, there is a "W" and the Roman numeral "II" that are not described in the specification.

2. In figure 2, there is an "L" and that is not described in the specification.

3. In figure 6B, there is an "H" that is not described in the specification. The

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities:

1. On page 2, line 23, there needs to be a colon after the word "follows" and the next sentence will need to be reworded.
2. On page 7, lines 20 & 22, and on page 15, lines 6 & 8, the letter "C" in the word chemical and the letter "F" in the word formula should be lower case.
3. On page 23, line 1, the word "no" should be "not."

Appropriate correction is required.

### ***Claim Objections***

Claim 11 is objected to because of the following informalities: the words "Chemical Formula" should not be capitalized. Appropriate correction is required.

Claim 17 is objected to because of the following informalities: claim 17 describes properties of chemical formula (2), however, these properties are listed in the specification regarding chemical formula (1). Although chemical formula (1) and chemical formula (2) in the specification are the same formula, there is no mention in the specification that the properties listed in claim 17 relate to chemical formula (2). The specification relates the properties in claim 17 to chemical formula (1). Claim 17 should be rewritten to include chemical formula (1) and not chemical formula (2). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

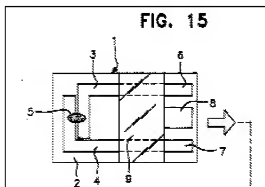
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

5 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-6, 8, 12 and 18 are rejected under 35 U.S.C. 103(a) as being obvious over Gotoh et al. (U.S. Pat. No. 6,071,391).

15 Regarding claims 1-6 and 18, Gotoh et al. teaches thin analysis tool for measuring glucose comprising: a reaction space for holding a sample liquid (5); a reagent portion that dissolves when the sample is held in the space (col. 14, lines 45-60); the first and second surfaces face each other (col. 17, lines 17-19) spaced at a distance; first and second electrodes (3 & 4) that are provided on one side of the first plate (2)(col. 1, lines 62-63); and a voltage is applied between the electrodes (col. 15, line 62).



Claims 1, 4 and 6 state that the facing distance between the surfaces is between 25  $\mu\text{m}$  and 45  $\mu\text{m}$ . In view of Gotoh's et al. general description (see col. 3, lines 39-44) of the distance between the surfaces being 100 $\mu\text{m}$  - 500 $\mu\text{m}$ , it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the  
5 general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ  
10 215 (CCPA 1980)(see MPEP § 2144.05, II). Therefore, it would have been obvious to a person of ordinary skill in the art to select an appropriate distance between the electrodes of Gotoh et al. to establish the size of the reaction chamber.

Regarding claim 3, Gotoh et al. teaches disposing both electrodes on the same plate (col. 16, lines 33-35).

15 Regarding claim 5, Gotoh et al. teaches disposing one electrode on each plate (col. 17, lines 30-33).

Regarding claim 8, Gotoh et al. teaches that the reagent portion includes an electron mediator and a redox enzyme (col. 4, lines 6-16).

Regarding claim 12, Gotoh et al. teaches that the redox enzyme has glucose  
20 dehydrogenation activity (col. 7, lines 11-13).

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al. in view of Heller et al. (U.S. Pat. No. 6,576,101).

Regarding claim 7, Gotoh et al. teaches a thin analyzing device but does not expressly teach the use of capillary force to move the sample.

However, Heller et al. recognizes that a sample in a reaction space may be moved by capillary force (col. 10, lines 64-67) when the dimensions are below 200  $\mu\text{m}$ .

5 Therefore, it would have been apparent to one of ordinary skill in the art that when optimizing the size of the facing distance of Gotoh et al., the reduced size resulted in capillary forces.

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al. in view of Leong et al. (U.S. Pat. No. 6,837,988).

10 Regarding claim 9, Gotoh et al. teaches a thin analyzing device, but does not teach the use of ruthenium as the electron mediator.

However, Leong et al. recognizes that a ruthenium compound can be used as a mediator agent (col. 12, lines 52-58).

The Courts have held that the selection of a known material, which is based upon  
15 its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). In addition, the combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR*  
20 *International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143).

Therefore, it would have been obvious to one of ordinary skill in the art to have substituted the known functionally equivalent ruthenium compound for the electron mediator of Gotoh et al. See MPEP 2144.06.

4. Claims 10, 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being  
5 unpatentable over Gotoh et al. in view of Leong et al. as applied above to claim 9 and in view of Nagakawa et al. (WO 03/025558, with reference to its English equivalent, U.S. Pat. No. 7,390,391).

Regarding claims 10, 11 and 13-17, Gotoh et al. and Leong et al. teach a thin analyzing device, but do not teach that the X in the ruthenium compound could be  $\text{NH}_3$ ,  
10 a halogen ion, CN, pyridine, nicotinamide, or  $\text{H}_2\text{O}$  and that  $n^+$  is the valence of an oxidized Ru(III) complex determined by a type of X. In addition, Gotoh et al. and Leong et al. do not teach that the molecular weight of cytochrome C is about 43 kDa and the subunit of glucose dehydrogenase has a molecular weight of about 60 kDa measured by SDS-polyacrylamide gel electrophoresis.

15 However, Nagakawa et al. (U.S. Pat. No. 7,390,391) teaches that a ruthenium compound could be  $\text{NH}_3$  or a halogen ion (col. 3, lines 63-67; col. 4, lines 1-4). Nagakawa et al. also teaches that the microbe may belong to the Burkholderia genus (col. 4, line 57). In addition, Nagakawa et al. teaches that the molecular weight of cytochrome C is about 43 kDa (col. 4, lines 43-45) and the molecular weight of GDH is  
20 about 60 kDa (col. 4, lines 38-39).

The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art.



See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). In addition, the combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR*

5 *International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143).

Therefore, it would have been obvious to one of ordinary skill in the art to have substituted the electron mediator and enzyme combination of Nagakawa et al. for the materials disclosed by Leong et al. and Gotoh et al. because the new materials reduced  
10 background current (see col. 2, lines 62-65).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Friday, 8am to 5pm  
15 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Sines can be reached on (571) 272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

5 For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JMD

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/Brian J. Sines/

Supervisory Patent Examiner, Art Unit 4111